K070878

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RG Medical Diagnostics

DIAGNOSTICS

JUN - 5 2007

Premarket 510(k) Summary

DataTherm® II

Submitter information:

Sponsor:

RG Medical Diagnostics
21130 Bridge Street
Southfield, MI 48034
1-248-750-0181 ph
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Contact Person: Ronald G. Le Tourneau
Date Prepared: 26 February, 2007

Device Name:

1. **Classification:** **General Hospital**
2. **Common Name:** **Clinical Electronic Thermometer**
3. **Proprietary Name:** **DataTherm® II Continuous Temperature Monitor**
4. **Classification:** **FLL – CFR 880.2910**
5. **Performance Standards:** **ASTM E1112-00 (2006), EN60601-1-2 (harmonized)**
6. **Predicate Device Information:**

   K001281, Geratherm Babywatch Temperature Monitor

   Manufactured by:
   Geratherm Medical AG
   Fahrenheitstrasse 1
   D-98716 Geschwenda, Germany

7. **Device Description:**

The DataTherm II Continuous Temperature Monitor (model HD-2300) consists of four components.

1. A control / display assembly measuring 3.16" X 2.37" X 0.71" with an LCD screen and 5 control keys (On/Off, Mode Selection, ▲(increase), ▼(decrease) and keyboard Lock). The interior electronic components consist of a circuit board, a battery compartment housing 2 - AAA batteries, a buzzer and LED alert light.

2. A disposable flexible temperature probe having a plug-in connector at one end and thermistor sensor at the other.

3. A USB interface connector cable that permits the transfer of stored and real-time temperature/time/day information to a PC computer screen.

4. Proprietary software that permits an individual patient's current temperature to be viewed and temperature/time/date information to be displayed and archived, if desired.

5. Intended Use:

The DataTherm II Continuous Temperature Monitor is intended to continuously measure, display and monitor human body temperature updating every 4 seconds. Additionally, it stores up to 140 temperature/time/day data sets that may be stored at a user-selected frequency range from once per minute to once every 24 hours in one minute intervals. The current temperature and stored information may be viewed on the LCD screen that is integrated into the instrument or, from a PC computer screen after installation of the DataTherm software to a PC. The DataTherm II is intended to be used on patients of all ages.

6. Comparison to Predicate Device

The subject device is substantially equivalent to the predicate device, the Babywatch (marketed as DataTherm®) K001281. Both the subject and predicate devices are designed and engineered by the same company, Geratherm AG. The two devices employ the same technology, display information, and use the same controls. The subject device differences include disposable temperature probes, larger batteries, added visual temperature alert LED, improved water repellency, expanded memory, expanded storage interval alternatives and the ability to view and archive time/temperature/date data on a PC computer in user named files.

7. **Discussion of Non-clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

The DataTherm II (model KD-2300) complies with EN 60601-1-2 "Electromagnetic Compatibility" and ASTM E1112-00 " Electronic Thermometer for Intermittent Determination of Patient Temperature" standards. In addition, the DataTherm II conforms to the harmonized standard for electronic safety established by the US FCC Part 15.

8. **Discussion of Clinical Tests Performed:**

Not Applicable

9. **Conclusions:**

The subject device and predicate devices provide the same functions and controls through employment of the same technology. Moreover, bench testing contained in this submission demonstrate that any differences in their characteristics do not present any new questions of safety or effectiveness. Thus, the DataTherm® II Continuous Temperature Monitor is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ronald G. Le Tourneau
President
RG Medical Diagnostics
21130 Bridge Street
Southfield, Michigan 48034

JUN - 5 2007

Re: K070878
Trade/Device Name: DataTherm® II Continuous Temperature Monitor
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: May 04, 2007
Received: May 07, 2007

Dear Mr. Le Tourneau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070878

Device Name: DataTherm® II Continuous Temperature Monitor

Indications For Use:

The DataTherm® II Continuous Temperature Monitor is used to measure and monitor human body temperature and for storing temperature data at adjustable, preset time intervals.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K070878